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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,695	04/12/2001	Michael F. Weiser	B0410/7277	7619

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EXAMINER

HAMILTON, LALITA M

ART UNIT	PAPER NUMBER
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3624

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,695

Applicant(s)

WEISER ET AL.

Examiner

Lalita M Hamilton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-7,9 and 11-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-7, 9, and 11-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Summary

On September 23, 2002, an Office Action was sent to the applicant rejecting claims 1-49. On March 24, 2003, the Applicant responded by amending claims 2, 9, 11, 18, 20, 22, 26-30, 38, 42, and 46 and canceling claims 1, 8, and 10.

Drawings

The objections set forth in the previous Office Action, paper no.6, has been withdrawn.

Specification

The disclosure is objected to because of the following informalities: The continuation data is not present in the first paragraph. Appropriate correction is required.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The Examiner has read the response to the missing abstract; however, the Examiner asks that the Applicant send in another copy of the abstract as it is missing from the file.

Claim Objections

Claims 11-17, 20-21, and 34-37 are objected to because of the following informalities: Claim 11 depends from canceled claim 1; claims 13-14, 20-21, and 34 depend on canceled claim 8; and 12, 15-17, 35-37 are objected because of their dependency on objected claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The rejections set forth in the previous Office Action have been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 2-7, 9, and 11-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Kim (6,007,544), as set forth in the previous Office Action. *Note: The date used for this reference is the filing date of June 14, 1996.*

Claim 49 is rejected under 35 U.S.C. 102(a) as being anticipated by Hussein (5,810,836).

Hussein discloses an implant device and method of implanting comprising the steps of providing a flexible spring body implant having sufficient longitudinal flexibility to

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absorb migratory forces applied on the device by surround tissue after implantation and inserting the flexible spring into the tissue (col.2, line 47-48) and (col.3, lines 35-40).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim in view of Whalen (4,130,904), as set forth in the previous Office Action.

Claims 30 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim in view of Wijay (5,824,059), as set forth in the previous Office Action.

Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim and Whalen as applied to claim 25 above, and further in view of Hussein (5,810,836), as set forth in the previous Office Action.

Claims 38-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hussein in view of Mori (5,466,242).

Hussein discloses the invention substantially as claimed and an alternative embodiment where the implant remains exposed at the surface of the tissue after implantation (fig.1); however, Hussein does not disclose a body having a proximal portion and a distal portion each defining a profile and wherein the profile of the proximal portion is larger than the distal portion, the device being delivered percutaneously or transthoracically, or applying a penetrating force to the implant and

implant delivery device combination such that the combination penetrates tissue to a clinically effective penetration depth to implant the device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the method of delivering the device percutaneously and transthoracically in order to provide an alternative means of delivery and to apply a penetrating force to the implant and implant delivery device combination in order to ensure that the combination penetrates tissue to a clinically effective penetration depth to implant the device.

Mori teaches an expandable coiled stent (fig.2: 1-2) that may be used in vascular systems (col.4, lines 40-42) having a proximal portion and a distal portion each defining a profile wherein the profile of the proximal portion is larger than the distal portion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a stent wherein the profile of the proximal portion is larger than the distal portion, as taught by Mori, as an alternative shape since Hussein discloses a flexible spring that may take on a variety of shapes and materials depending on what type of pressure and how the pressure is applied to the stent (col.2, line 48).

Claims 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hussein in view of Mori and Murphy-Chutorian ('133).

Hussein discloses the invention substantially as claimed; however, Hussein does not disclose a body having a proximal portion and a distal portion each defining a profile and wherein the profile of the proximal portion is larger than the distal portion or the method of applying surgical adhesive at the site of the implant after implantation. It is inherent that adhesive may be applied to the body prior to implantation. Mori teaches

an expandable coiled stent (fig.2: 1-2) that may be used in vascular systems (col.4, lines 40-42) having a proximal portion and a distal portion each defining a profile wherein the profile of the proximal portion is larger than the distal portion. Murphy-Chutorian teaches a method of securing a stent to the tissue using surgical adhesive (col.13, lines 45-59). It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate a stent wherein the profile of the proximal portion is larger than the distal portion, as taught by Mori, as an alternative shape since Hussein discloses a flexible spring that may take on a variety of shapes and materials depending on what type of pressure and how the pressure is applied to the stent (col.2, line 48) and the method of applying surgical adhesive at the site of the implant prior to or after implantation in order to provide an alternative means of preventing migration of the device.

Response to Arguments

Applicant's arguments filed on March 24, 2003 have been fully considered but they are not persuasive. The Applicant has argued that the Kim reference does not disclose an implant device having a proximal portion defining a larger profile than the distal portion. In response, Kim discloses what the Examiner is interpreting as a proximal portion (fig.38B: 402) defining a larger profile than the distal portion (404), which is similar to Applicant's fig.8. Although the Applicant has argued that fig.38B is "merely a transformation of the device shown in fig.38A", fig.38B still clearly reads onto the invention substantially as claimed. Further, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does

not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations *Ex parte Masham*, 2 USPQ2d 1647 (1987).

With regard to the arguments pertaining to claim 38 and the Hussein reference, the Examiner has incorporated a new rejection in response to the amendment to this claim (please reference rejection above).

The Applicant has argued that Hussein does not disclose forming implants to have sufficient longitudinal flexibility to absorb migratory forces applied to the surrounding tissue. In response, on p.6, lines 15-31 of the Applicant's specification, the Applicant states that in the case of flexible helical springs, variables such as filament diameter, spacing between individual coils and filament material may be altered to provide adequate flexibility in a device to reduce migration or by using two or more different filament materials along the length of the filament that have different moduli of elasticity. Hussein discloses a device that diameter and spacing of individual coils may be varied using a thermally deformable material (col.27, line 50 to col.28, line 17), which the Examiner is interpreting as having "sufficient longitudinal flexibility to resist migratory forces applied to surrounding tissue".

With regard to arguments pertaining to the Whalen and Wijay references, the Applicant has argued that the claims 25-37 depend from claim 2, which was rejected under the Kim reference and that Kim does not disclose the limitation of the proximal portion having a larger profile than the distal portion. In response, please reference the remarks above.

With regard to claims 39, 41, 43-44, and 46-48, the Applicant has argued that the neither Hussein nor Murphy-Chutorian disclose or teach an implant having a proximal portion profile that is larger than the distal portion. In response to the amendment to the claims incorporating this limitation, please reference the rejection above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lalita M Hamilton whose telephone number is (703) 306-5715. The examiner can normally be reached on Tuesday-Thursday (8:30-4:30).

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The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-6101 for regular communications and (703) 746-6101 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-

2272


LMH

June 14, 2003



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